

### REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the remarks which follow.

In his Office Action of July 2, 2010, the Examiner found applicants' Response to Requirement for Restriction and Preliminary Amendment of March 23, 2010 to not be fully responsive to the prior Office Action of September 25, 2009. Applicants have accordingly deleted subparagraph h) by amendment herein in response to the Examiner's requirement.

Applicants hereby elect to prosecute the claims in Group I, namely, claims 24 – 33 and 37 – 40 in the outstanding Office Action. This election is made with traverse.

Group II, which includes claims 34-36, relates to a subcutaneous implant. The traverse is based on the grounds that the objection to the lack of a single general inventive concept is groundless.

As a matter of fact, the Examiner based his reasoning commencing from the incorrect assumptions that Claims 24-33 are drawn to a process for making plasticized PLGA. Indeed, said claims are “product-by-product claims”, within the meaning given by MPEP 2113, i.e., claims wherein a product is claimed, being defined by the process. In sum, claim 24 is a **Product claim**.

As far as claims 34-36 (Group II) are concerned, the subcutaneous implants are products comprising the plasticized PLGA according to Claim 24 and active principles. Therefore, said implants are claimed to include all of the features of the foregoing claim 24. From a practical point of view, claim 34 relates to a product claim containing the product of claim 24 and, therefore, containing all the features of claim 24.

According to “unity of invention” requirements, a patent application can contain two product claims, for instance product A and Product B, but one must include all the features of the one, i.e., Product B must include Product A. In any case, Product B is a

different Product from A and, logically, it contains another element. As a matter of fact, in this case the product A is the PLGA plasticized with ethanol, and product B is the subcutaneous implant, which contains not only PLGA plasticized with ethanol, but also bioactive ingredients.

The **plasticized PLGA** itself, i.e., the entirety of claim 24, is the **special technical feature** corresponding to the **single general inventive concept** of the current application and is contained in claim 34.

This also means that PCT Rule 13.1, as mentioned by the Examiner, concerning the requirement of “unity of invention” is met.

PCT Rule 13.2 specifically recites:

“...the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

The Examiner states that said PCT Rule 13.2 is not fulfilled because Group II claims bioactive agents which are not present in plasticized PLGA of Group I.

As clarified above, this derives from a misinterpretation of the claimed subject-matter. Actually, the plasticized PLGA in claims 24-33 is a product, and subcutaneous implants comprise said product and active principles.

In view of the above, Applicants are persuaded and maintain that the technical features of the plasticized PLGA according to claim 24 are **special features** that correspond to a **single general inventive concept**. In this regard, Applicants submit that there remains no room for the Examiner to argue a lack of unity which therefore results, in turn, in an unjustifiable Requirement for Restriction.

Since claims 34-36 which are directed to the nonelected Group II include all of the limitations of the allowable product claims 24-33 and 37-40, claims 34-36 should be considered for rejoinder.

### **CONCLUSION**

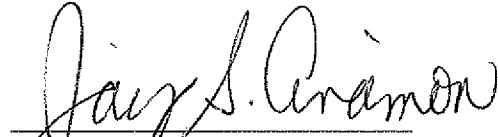
In view of the foregoing, Applicants strongly believe that the currently pending claims meet the requirements of unity of invention on the grounds that the arguments provided fully overcome the objections raised in the outstanding Office Action.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

ABELMAN, FRAYNE & SCHWAB  
Attorneys for Applicant

By

  
Jay S. Cinnamon  
Attorney for Applicant  
Reg. No. 24,156

666 Third Avenue  
New York, NY 10017-5621  
Tel.: (212) 949-9022  
Fax: (212) 949-9190